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K003323

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE COMPOSIX E/X MESH

A. Submitter Information

Submitter's Name:	Davol, Inc.
Address:	Subsidiary of C. R. Bard, Inc. 100 Sockanossett Crossroad Cranston, RI 02920
Telephone:	401-463-7000 ext. 2263
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Contact Person:	Paula E. Bulger
Date of Preparation:	September 28, 2000

B. Device Name

Composix Kugel Mesh

C. Predicate Device Name

Trade name: Kugel Mesh (Davol Inc.)
Composix E/X (Davol Inc.)

D. Device Description

The proposed Composix Kugel Mesh will be oval in shape and is a self-expanding, two-layered mesh with an extruded monofilament PET polymer "ring". The mesh is constructed of knitted polypropylene. monofilament approximately 0.006" in diameter. The monofilament PET polymer "ring" adds stability to the device enabling greater simplicity and assurance in the proper placement of the patch. A single layer of expanded polytetrafluoroethylene (ePTFE) is attached to the polypropylene mesh. The attachment is accomplished with an interlocking stitch using polytetrafluoroethylene (PTFE) monofilament, and the peripheral edge of the polypropylene mesh will be heat sealed to the ePTFE layer.

E. Intended Use

The Composix Kugel Mesh is intended for use in all hernia repairs requiring reinforcement with a nonabsorbable support material.

F. Summary of Similarities and Differences in Technological Characteristics, Performance and Intended Use

The Composix Kugel Mesh and the predicate Kugel Mesh have the same intended use, which is intended for the use in all forms of Hernia repair requiring reinforcement with a nonabsorbable support material. The technological characteristics are the same or similar to the predicate devices in that the materials used to manufacture these products are similar to the predicate polypropylene and ePTFE meshes. Differences include the number of layers of mesh.

G. Performance Data

Biocompatibility and bench testing have been completed and support the safety and effectiveness of the Composix Kugel Mesh for its intended use.

As previously mentioned, the Composix E/X predicate and the proposed Composix Kugel devices use similar materials and manufacturing methods for production. The Composix Kugel and the Composix E/X Mesh have a single layer of expanded polytetrafluoroethylene (ePTFE) and is attached to the polypropylene mesh with an interlocking stitch using polytetrafluoroethylene (PTFE) monofilament. The peripheral edge of the polypropylene mesh is heat sealed to the ePTFE layer. The ePTFE and the PTFE monofilament used in the predicate Composix E/X device are the same as the ePTFE and PTFE monofilament used in the proposed Composix Kugel device. The polypropylene mesh used in the proposed Composix Kugel device is the same material as the polypropylene used in the predicate Kugel device

The biocompatibility test results show that the material used in the design and manufacture of the device are non-toxic and non-sensitizing to biological tissues consistent with their intended use. Laboratory test results demonstrate that the materials chosen and the design utilized in manufacturing the Composix Kugel Mesh will meet the established specifications necessary for consistent performance during their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 2 2001

Ms. Paula E. Bulger
Senior Regulatory Affairs Associate
Davol, Inc.
Subsidiary of C. R. Bard, Inc.
100 Sockanossett Crossroad
P.O. Box 8500
Cranston, Rhode Island 02920

Re: K003323
Trade Name: Composix Kugel Mesh
Regulatory Class: II
Product Code: FTL
Dated: October 23, 2000
Received: October 24, 2000

Dear Ms. Bulger:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 003323

Device Name: Composix Kugel Mesh

Indications for Use: **Intended for the use in all forms of Hernia repair requiring reinforcement with nonabsorbable support material.**

(Please do not write below this line – Continue on another page if needed)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X **OR** **Over-the Counter Use** _____

(Per 21 CFR 801.109)

for _____

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003323

(Optional Format 1-2-96)